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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorric M. Happ	50623.132	4580

7590 05/25/2004

Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,036

Applicant(s)

HAPP, DORRIE M.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/17/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment filed 02/17/04 and IDS filed 02/17/04.

Claims 2-5, 7-11, 14-17, 19, 21 and 23-28 are pending.

Claim Rejections - 35 USC § 112

1. The rejection claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the amendment to claim 14 filed 02/13/04 overcomes the rejection.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 2-5, 7-11, 14-17, 19, 21 and 23-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Harish et al. (US 2002/0122877 A1).

Harish discloses a “method of forming a coating onto an implantable device or endothelial prosthesis, such as stent” and the coating composition comprises an active ingredient (abstract) dispersed in a blended composition of polymer and solvent (page 2, paragraphs [0024] – [0026] to page 3, paragraphs [0029] and [0030]). The active ingredients are antiproliferative agents such as actinomycin, antineoplastic agents such as paclitaxel and docetaxel and antimetabolic agents such as vincristine (page 3, paragraphs [0030] and [0031]). The coating composition may contain radiopaque elements or radioactive isotopes (page 1, paragraph [0012]) and an example of a radiopaque element is gold (page 4, paragraph [0034]). The coated medical implantable device or endothelial prosthesis is optionally coated with a primer layer, where the

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primer layer is between the surface of the device and coating composition layer that contains dispersed active ingredient; and where the primer layer is polymeric (paragraphs [0042] to [0045]). An optional topcoat, which may or may not contain active ingredient is formed onto at least a portion of the coating layer (paragraphs [0049]).

The instant generic claim 5 is directed to a coating composition that comprises a drug-polymer composition/layer, a light/UV-protective compound contained in the coating layer and a top-coat formed over the coating drug-polymer layer. "For medical device, the coating having increased resistance to light and/or UV-radiation," does not carry patentable weight in a coating composition.

In Harish, a teaching of radiopaque element such as gold meets the limitation of the presence of light/UV-protective compound. This is supported by claim 11 where gold is recited as a light and/or UV-protective compound. Harish in paragraph [0049] discloses that an optional top coat containing or not containing active ingredient is formed on at least a portion of the coating layer. The teachings of Harish meet the limitations of the claims.

Applicants argue that Harish fails to teach the limitation of "light and/or UV-protective compound included in the top coat layer."

4. Applicant's arguments filed 02/13/04 have been fully considered but they are not persuasive. Harish discloses a top coating material that has dispersed within it active agent and the UV-protective compound qualifies as an active compound. Claims 8 and 19 previously objected to are now rejected. Applicants are respectfully referred to the rejection above.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Harish et al. (US 6,503,556 B2), Hossainy et al. (US 2001/0014717 A1) and Pacetti


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et al. (US 2002/0123801 A1), all of which disclose medical device such as stent that is coated with polymeric composition that comprises active agents and light and/or UV-protecting compound, an optional primer composition is deposited on the surface of the device between the coating composition and the stent and an optional top-coat of barrier polymer coating is disposed on the coating composition (see entire documents).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Blessing Fubara
Patent Examiner
Tech. Center 1600